OCT 1 6 2001

Special 510(k) Summary
for
Sens-A-Ray System with ProImage Software

K013176

1. SPONSOR

AFP Imaging Corporation
250 Clearbrook Road
Elmsford, NY 10523

Contact Person: Tzipora Halevi
Telephone: 914-592-6100

Date Prepared: September 21, 2000

2. DEVICE NAME

Proprietary Name:	Sens-A-Ray Digital Dental X-Ray System with ProImage Software
Common/Usual Name:	Accessory to Extraoral X-Ray System
Classification Name:	Extraoral Source X-Ray System Accessory

3. PREDICATE DEVICES

AFP Imaging Corporation Sens-A-Ray System K923067

4. DEVICE DESCRIPTION

The ProImage Software is essentially identical to the Sens-A-Ray software described in K923067. (K923067 was submitted to FDA by the former owner of AFP Imaging, Regam Medical Systems AB.) The AFP Imaging ProImage Software and Sens-A-Ray System are intended to be used in conjunction with standard X-Ray systems. X-Ray images are sent by a digitized processor to a computer screen for image presentation. As with the Sens-A-Ray Software, the ProImage Software provides and controls the following functions:

- A patient/image database, which logs a patient's statistical and image data
- Image exposure
- Image storage
- Image processing
- Image retrieval and post-processing
- Image hardcopy

The modifications to the Sens-A-Ray software involve enabling video images and X-ray images to be processed and manipulated within the same software package. The minor modifications involve better database search and structure to allow the user to catalog patient images in an easier and more intuitive format. The other changes involve feature improvements resulting from user input. The feature improvements include:

- Colorizing image, auto-contrast, re-expose, and "view histogram" functions
- Importing multiple images and adjusting the size and resolution of images
- Adding an endodontic mode which allows full-screen X-rays

The modifications above were made to accommodate more advanced digital X-ray systems and to provide the user with better imaging capabilities within a single software package. These modifications remain within the scope of the intended use and fundamental technology of the original Sens-A-Ray system.

The ProImage Software is intended for use with a sensor unit, image unit, and image grabber that were previously cleared under K923067. The ProImage Software is also compatible with the AFP IntraOral camera, subject of K922942 and other legally marketed intraoral cameras.

5. INTENDED USE

The ProImage Software is intended to be used with the Sens-A-Ray system and standard digital dental X-ray systems and computer stations for system operation, archive data storage, image capture and enhancement, and patient data and support.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The AFP Imaging ProImage Digital Dental X-Ray System Software is similar in intended use and fundamental technology to the Sens-A-Ray Software, subject of K923067. The AFP ProImage Software and the predicate Sens-A-Ray Software have the same intended use. They are both intended to be used with digital dental imaging systems for the capture, evaluation, and storage of high quality digital dental X-rays using existing X-ray equipment. Both devices are indicated for patients receiving routine dental radiography.

The AFP ProImage Software and the predicate device are operational software packages that support system operation, image capture, and enhancement, patient data, and support. They are both installed into digital dental systems intended for use with standard X-ray equipment.

The AFP Imaging ProImage Software and the predicate devices have essentially identical performance characteristics. These devices use an extraoral source of X-rays for intraoral images in dental radiography. They provide a means for capturing, enhancing, and delivering dental images for viewing and storage

7. TESTING

Verification and validation testing was successfully performed to confirm that the modified software functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

AFP Imaging Corporation
% Mary-McNamara-Culline, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K013176
Trade/Device Name: AFP Imaging Sens-A-Ray Digital Dental X-Ray System Software
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: September 21, 2001
Received: September 24, 2001

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013176

Device Name: AFP Imaging Sens-A-Ray System with ProImage Software

Indications for Use:

The AFP Imaging Sens-A-Ray Digital Dental X-Ray System with ProImage Software is intended for use with standard digital dental X-ray systems and computer stations for system operation, archive data storage, image capture and enhancement, and patient data and support.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013176

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)